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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,930	10/11/2001	Michael Poirier	560.09-US1	4572

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,930

Applicant(s)

POIRIER ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al., 5,374,395.

Robinson et al. disclose a container having an outermost wall that is formed at least in part by a flexible sheet (i.e., the test packs formed of a flexible plastic, col. 4, lines 35-37), the container further including a fluid receiving port (220, col. 37, line 41), a fluid discharge port (opening leading into the second reaction area (col. 38, lines 45 and 54), and a plurality of compartments (first reaction area and second reaction area, col. 38, lines 54-55; see also col. 34, lines 9-10, and 21) fluidly coupled to at least one of the fluid receiving port and the fluid discharge port (through opening in col. 38, line 54); wherein the fluid port is configured to receive a continuous flow of a biological fluid (i.e., it is capable of receiving a continuous flow of biological fluid), and wherein the fluid discharge port is capable of emitting a continuous flow of the biological fluid that is at least partially depleted from a target antigen while the fluid receiving port receives the continuous flow of the biological fluid (col. 38, lines 48-54, disclosing use of magnets to

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pull metal beads out of the first reaction area); wherein at least one of the compartments further comprises a plurality of magnetic beads (col. 38, line 50, and col. 33, line 64); and wherein the target antigen is capable of being separated from the biological fluid using a magnetic force and an automatic mechanical force (col. 38, lines 48-49, disclosing magnets 606 to move the magnets, and lines 47-49, disclosing rollers 614 and 616 to move the solution), wherein the magnetic force and the automatic mechanical force are transmitted through the flexible sheet (col. 38, lines 47-49).

As to claim 2, at least one of the compartments includes an elution fluid (col. 34, lines 9-11).

As to claim 4, at least one of the compartments further includes a port that allows draining of the at least one of the compartments (col. 38, lines 51-52, disclosing pushing liquid to the second reaction area).

As to claim 5, the biological fluid comprises whole blood (the container is capable of receiving whole blood; see also col. 1, line 68). (The Office notes that the container only needs to be capable of receiving whole blood/biological fluid, according to claim 1, from which claim 5 depends.)

As to claim 6, the target antigen is present on a bacterium (the container is capable of receiving a biological fluid that includes a bacterium; see also col. 1, line 13.) (The Office notes that the container only needs to be capable of receiving biological fluid that includes a bacterium, according to claim 1, from which claim 6 depends.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al., 5,374,395.

Robinson et al. disclose the invention substantially as claimed (see above), except for the affinity marker being an antibody.

Robinson et al. that hybridization assays are preferred, but antibody methods are well known for detecting microorganisms (col. 1, lines 16-18, col. 42, lines 4-9.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute an antibody probe for a nucleotide probe to detect microorganisms because Robinson et al. teaches that it is well known that antibody probes are used for detection of microorganisms, and is an alternative to hybridization assays for the detection of microorganisms.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. (Robinson et al. teaches that a magnetic force

and an automatic mechanical force are transmitted through the flexible top sheet, as described above.)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

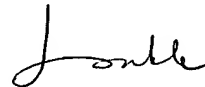
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/13/05